

Notice of Allowability	Application No.	Applicant(s)	
	10/544,103	GRIENGL ET AL.	
	Examiner HERBERT J. LILLING	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to November 19, 2007.
2. The allowed claim(s) is/are 1-10.
3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>08-19-05;11-19-07</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 	<ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>Jan 14 & 17, 2008</u> 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____.
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EXAMINER'S AMENDMENT

An examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Amendment to Claims:

Claim 11 has been cancelled.

In **claim 4, line 3, delete**: "crude or purified enzymes, recombinant enzymes," **and after** "immobilized cells" **delete** "or enzymes"

AMENDMENTS TO THE SPECIFICATION

Insert a heading at page 1, line 3, of the specification:

----- **BACKGROUND OF THE INVENTION** -----.

Insert a heading at page 2, line 21, of the specification:

----- **SUMMARY OF THE INVENTION** -----.

Insert the following headings and description of the figures starting at page 2, line 32, of the specification:

----- **BRIEF DESCRIPTION OF THE DRAWINGS**

FIGURE 1 illustrates the map of the plasmid pMS470Nhase7.3 (6606 bp).

FIGURE 2 illustrates the map of the plasmid pMS470-33/3/1/11 (5557 bp).

DETAILED DESCRIPTION OF THE INVENTION -----.

Approved by Attorney Gary R. Tanigawa on February 1, 2008.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**, or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ATTACHMENT TO INTERVIEW OF JAN 14, 2008 & Jan 17, 2008

The following amendments have been discussed for allowance of the instant application:

Claim 11 to be cancelled.

Amendment to Claims:

In claim 4, line 3, delete: "crude or purified enzymes, recombinant enzymes," and after "immobilized cells" delete "or enzymes".

In view of the claimed subject matter with respect to claim 1 and claim 11, a restriction has been required between the following inventions:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 5-10, drawn to a method for producing chiral .alpha.-hydroxycarboxylic acids, which comprises converting (R)- or (S)-cyanohydrins by enzymatic hydrolysis in the presence of *Rhodococcus erythropolis NCIMB 11540* into the conjugate (R)- or (S)-.alpha.-hydroxycarboxylic acids. , classified in class 435, subclass 280.
- II. Claim 11, drawn to a process as claimed in claim 4, characterized in that, as recombinant enzyme, use is made of an enzyme obtained by expression of the pMS470 plasmid system in a suitable host cell. classified in class 435, subclass 183.

Claim 4 will be examined with the elected invention.

Applicant reserves the right to file a divisional to the non-elected cancelled subject matter. It was noted that the cancelled non-elected subject matter do not further limit claim 1 since the claim requires the "enzymatic hydrolysis in the presence of *Rhodococcus erythropolis NCIMB 1154*", which microorganism is not present in the cancelled claimed subject matter. The requirement in the previous office action was a

restriction between the enzymes and the microorganism cells and not an election of species.

Attorney will contact Applicant for approval which claims will be considered for allowance. Attorney contacted this Examiner **on January 17, 2007 to approve** of the above amendments and the right to file divisional(s) to the non-elected cancelled claims drawn to two inventions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL

(571) 272-0918

Art Unit **1657**

January 17, 2008

Herbert J. Lilling
Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657

REASONS FOR ALLOWANCE

The following is an Examiner's Statement of Reasons for Allowance:

Any comments considered necessary by applicant must be submitted no later than the Payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

The references do not anticipate the claimed subject matter. In addition, the references alone or further in view of each other suggest or motivate one of ordinary skilled in the art to produce chiral alpha hydroxycarboxylic acids by the enzymatic hydrolysis in the presence of *Rhodococcus erythropolis* NCIMB 11540 which claims are patentable in view of The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Furthermore, in light of the Supreme Court's recent decision in *KSR International Co. v. Teleflex Inc (TFX)* ., 82 USPQ2d 1385 (2007) based on the reasoning may still include the established Court of Appeals for the Federal Circuit standard that a claimed invention may be obvious if the examiner identifies a prior art teaching, suggestion, or motivation (TSM) to make it. However, the Guidelines explain that there is no

requirement that patent examiners use the TSM approach in order to make a proper obviousness rejection. Furthermore, the Guidelines point out that even if the TSM approach cannot be applied to a claimed invention that invention may still be found obvious.

If there are any differences with respect to the claimed subject matter and the general knowledge pertaining to the art in the area, that these differences would have been *prima facie* obvious to one of ordinary skill in the pertinent art whether it was based on the art of record or claimed subject would have obvious for the "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results".

Further in view of "In U.S. v Adams...." Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the filed, the combination must do more than yield a predictable result."

Furthermore in view of ".Sakraida v. AG Pro Inc., ...the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious."

The Supreme stated the following:

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, 35 USC 103 bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve a similar device in the same way, using the technique is obvious unless its actual application is beyond his or her skill."

The KSR Decision requires rationales to support the rejections under 35 USC 103. The first issue is to analyze the Graham factual inquires as noted above for obviousness based of the prior art but the prior art is not limited to references but includes the basic knowledge and understanding of one skill in the pertinent art. Thus, the prior art alone or in combination does not have to teach or suggest or motivate one all of the limitations of the claimed limitations but there must be some rationale to explain these differences would have been obvious to one of ordinary skill in the art.

An extensive search and examination was required in view of the above Supreme Court decision to determine the issues for obviousness as to any rationale to reject the process claims. The prior art do not support **any reasonable** rationale to reject the instant claims which have been allowed.

Thus, Claims 1-10 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**, or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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January 14, 2008

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